UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION
PREVENTION

March 25, 2016

MEMORANDUM

Subject: Efficacy Review for CPPC Tsunami, EPA Reg. No. 67619-12; DB Barcode: D430984.

From: Ibrahim Laniyan, Ph.D.
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To: Demson Fuller RM32
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Applicant: Clorox Professional Products Company
c/o PS&RC
P.O. Box 493
Pleasanton, CA 94566-0803

Formulation from the Label:

Active Ingredient	% by wt.
Sodium hypochlorite	0.55 %
Other Ingredients:	99.45 %
Total	100.00 %

I. BACKGROUND

The product, Tsunami (EPA Reg. No. 67619-12) is an EPA-registered disinfectant towelette (bactericide, virucide, tuberculocide, sporicide, and fungicide), for use on hard, non-porous surfaces in hospitals, veterinary offices, dental practices, and medical settings. The applicant requested to amend the registration of this product to add claims against additional microorganisms. Additional studies were provided to support efficacy against *Clostridium difficile* in the presence of a soil load. Label directions indicate the product is effective as a "one-step" disinfectant. Studies were conducted at Accuratus Lab Services, located at 1285 Corporate Center Drive, Suite 110, Eagan, MN 55121 and MicroBioTest (Division of Microbac Laboratories, Inc.), 105 Carpenter Drive, Sterling, VA 20164.

This data package identified as D430984 contained a letter from the applicant to EPA (dated November 20, 2015), EPA Form 8570-1 (Application for Pesticide), EPA Form 8570-34 (Certification with Respect to Citation of Data), EPA Form 8570-35 (Data Matrix), an Efficacy Discussion Volume, 12 new studies (MRID Nos. 49749002 through 49749013), Statements of No Data Confidentiality Claims for each study, and the proposed label.

II. USE DIRECTIONS

The product is designed for disinfecting hard, non-porous surfaces, including: IV stands, bed pans, coated pillows and mattresses, desks, gurneys, stretchers, wheelchairs, dental surfaces, veterinary care surfaces, appliances, bathtubs, cabinets, chairs, counter tops, cribs, diaper pails, doorknobs, exterior toilet and urinal surfaces, floors, garbage cans, grocery carts, high chairs, keyboards, shower doors, showers, sinks, tables, toys, and walls. The proposed label indicates the product may be used on hard, non-porous surfaces, including: enamel, Formica, glass, glazed ceramic, glazed porcelain, metal (e.g., chrome, stainless steel), laminated surfaces, Marlite, plastic, porcelain enamel, synthetic marble, and vinyl.

Directions on the proposed label provide the following information regarding use of the product:

> **As a Disinfectant**: Wipe surface to be disinfected. Use enough wipes for treated surface to remain visibly wet for the contact time listed below -or- on label. Let air dry. Gross filth should be removed prior to disinfecting.

Directions on the proposed label provided the following directions for use of the product against *Clostridium difficile* spores:

> Wipe surface to be disinfected. Use enough wipes for treated surfaces to remain visibly wet for 3 minutes. Let air dry. Gross filth should be removed prior to disinfecting. Special Instruction for Cleaning Prior to Disinfection against *Clostridium difficile* spores. Personal Protection: Wear appropriate barrier protection such as gloves, gowns, masks, or eye covering. Cleaning Procedure: Fecal matter/waste must be thoroughly cleaned from surfaces/objects before disinfection by application with product. Cleaning is to include vigorous wiping and/or scrubbing, until all visible soil is removed. Special attention is needed for high-touch surfaces. Surfaces in patient rooms are to be cleaned in an appropriate manner, such as from right to left or left to right, on horizontal surfaces, and top to bottom, on vertical surfaces to minimize spreading of the spores. Restrooms are to cleaned last. Do not reuse soiled cloths.

III. AGENCY STANDARDS FOR PROPOSED CLAIMS

Antimicrobial Products for Use on Hard Surfaces Using Pre-saturated or Impregnated Towelettes: Towelette products represent a unique combination of antimicrobial chemical and applicator, pre-packaged as a unit in fixed proportions. As such, the complete product, as offered for sale, should be tested according to

the directions for use to ensure the product's effectiveness in treating hard surfaces. The standard test methods available for hard surface disinfectants and sanitizers, if followed exactly would not closely simulate the way a towelette product is used. Agency guidelines recommend that a simulated-use test be conducted by modifying the standard test methods. Agency guidelines further recommend that instead of spraying the inoculated surface of the carrier, the product should be tested by wiping the surface of the carrier with the saturated towelette, and then sub-culturing the slides after a specified holding time. Performance standards of the standard test methods must be met. These Agency standards are presented in EPA Pesticide Assessment Guidelines, Subdivision G, §91-2(h), Pre- saturated or impregnated towelettes; and the April 12, 2001 EPA Memorandum, Draft Interim Guidance for Non-Residual Sanitization of Hard Inanimate Food Contact Surfaces Using Pre-Saturated Towelettes.

Disinfectant With sporicidal activity against *Clostridium difficile:* The Agency has established interim guidance for the efficacy evaluation of antimicrobial products (e.g., dilutable products, ready-to-use products, spray products, vapor, gases, and towelettes) that are labeled for use to treat hard, non-porous surfaces in healthcare settings contaminated with spores of *Clostridium difficile*. The effectiveness of such a product must be substantiated by data derived from ASTM E 2197: Standard Quantitative Carrier Test Method to Evaluate the Bactericidal, Fungicidal, Mycobactericidal, and Sporicidal Potencies of Liquid Chemical Germicides. Modifications to each test method will be necessary to specifically accommodate spores of *Clostridium difficile*. Because *Clostridium difficile* is an obligate anaerobe, testing should ensure adequate incubation conditions for the recovery of viable spores. Three product batches should be tested at the lower certified limit(s) (LCL) listed on the confidential statement of formula (CSF) of the product. The toxigenic strains, ATCC 43598, of *Clostridium difficile* must be used for testing. For towelette and spray formulations, the Agency will accept testing of the liquid expressed directly from towelettes or collected directly from spray containers using one of the quantitative methods and conditions specified above. All products should be tested with a 3-part soil load incorporated into the test inoculum by adding 25 µl of 5% bovine serum albumin, 35 µl of 5% yeast extract and 100 µl of 0.4% mucin to 340 µl of the spore suspension. Results must show a minimum 6 log reduction of viable spores in 10 minutes or less. For towelette products, wetness determination test will be used to generate the contact time. Control carrier counts must be greater than 10^6 spores/carrier. The titer and purity of the final spore preparation must be $>10^8$ spores/mL, and >95% spores. ASTM Standard E2839 specifies procedures for achieving the 95% purity. The acid resistance of purified spores should be assessed against 2.5 M hydrochloric acid (see ASTM Standard E2839). The spores are considered acid-resistant if a log reduction of 0-2 is exhibited following 10 minutes of exposure to 2.5 M HCl.

Disinfectants for Use on Hard Surfaces in Hospital or Medical Environments: Effectiveness of disinfectants for use on hard surfaces in hospital or medical environments must be substantiated by data derived using the AOAC Use-Dilution Method (for water soluble powders and liquid products) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray products) or the AOAC Hard Surface Carrier Test. Sixty carriers must be tested with each of 3 product samples, each with an active ingredient level at the lower certified limit (LCL), as specified on the Confidential Statement of Formula (CSF), representing 3 different batches against a mean log density of at least 6 for *Staphylococcus aureus* (ATCC 6538) and *Pseudomonas aeruginosa* (ATCC 15442). To support products labeled as “disinfectants,” killing on 59 out of 60 carriers for germicidal spray testing is required to provide effectiveness at the 95% confidence level. To pass performance requirements when using AOAC Hard Surface Carrier Test, tests must result in killing in 58 out of each set of 60 carriers for *Staphylococcus aureus* (ATCC 6538); 57 out of each set of 60 carriers for *Pseudomonas aeruginosa* (ATCC 15442) within ten minutes. For AOAC Use-Dilution testing, testing for each lot should be conducted on a different day. Thus, a total of three tests for *Staphylococcus aureus* and three tests for *Pseudomonas aeruginosa* are necessary. Sixty carriers are required per test, without contamination in the subculture media. The performance standard for *Staphylococcus aureus* is 0-3 positive carriers out of sixty. The performance standard for *Pseudomonas aeruginosa* is 0-6 positive carriers out of sixty. To be deemed an effective product, the product must pass all tests for both microbes.

Disinfectants for Use on Hard Surfaces in Hospital or Medical Environments (Additional Bacteria): Effectiveness of disinfectants against specific bacteria other than those named in the AOAC Use- Dilution Method, AOAC Germicidal Spray Products as Disinfectants Method, AOAC Fungicidal Test, and AOAC Tuberculocidal Activity Method, must be determined by either the AOAC Use-Dilution Method or the AOAC Germicidal Spray Products as Disinfectants Method. Ten carriers must be tested against each specific microorganism with each of 2 product samples, representing 2 different product lots at LCL. To support products labeled as "disinfectants" for specific bacteria (other than those bacteria named in the above test methods), killing of the specific microorganism on all carriers is required.

Disinfectants for Use as Fungicides (Against Pathogenic Fungi, Using a Modified Method): The effectiveness of liquid disinfectants against specific pathogenic fungi must be supported by efficacy data using an appropriate test. The AOAC Use-Dilution Method (for water soluble powders and liquid products) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray or towelette products) may be modified to conform to appropriate elements in the AOAC Fungicidal Test. The inoculum in the test must be modified to provide a concentration of at least 10^6 conidia per carrier. Ten carriers on each of 2 product samples representing 2 different product lots at LCL must be employed in the test. Killing of the specific pathogenic fungi on all carriers is required.

Note: As an interim policy, EPA is accepting studies with dried carrier counts that are at least 10^4 for *Trichophyton mentagrophytes*, *Aspergillus niger*, and *Candida albicans*. EPA recognizes laboratories are experiencing problems in maintaining dried carrier counts at the 10^6 level. This interim policy will be in effect until EPA determines that the laboratories are able to achieve consistent carrier counts at the 10^6 level.

Virucides: The effectiveness of virucides against specific viruses must be supported by efficacy data that simulates, to the extent possible in the laboratory, the conditions under which the product is intended to be used. Carrier methods that are modifications of either the AOAC Use-Dilution Method (for liquid disinfectants) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray disinfectants) must be used. To simulate in-use conditions, the specific virus to be treated must be inoculated onto hard surfaces, allowed to dry, and then treated with the product according to the directions for use on the product label. One surface for each of 2 different product lots of disinfectant at LCL must be tested against a recoverable virus titer of at least 10^4 from the test surface for a specified exposure period at room temperature. Then, the virus must be assayed by an appropriate virological technique, using a minimum of four determinations per each dilution assayed. Separate studies are required for each virus. The calculated viral titers must be reported with the test results. For the data to be considered acceptable, results must demonstrate complete inactivation of the virus at all dilutions. When cytotoxicity is evident, at least a 3-log reduction in titer must be demonstrated beyond the cytotoxic level.

Supplemental Claims: An antimicrobial agent identified as a "one-step" disinfectant or as effective in the presence of organic soil must be tested for efficacy with an appropriate organic soil load, such as 5% serum.

IV. BRIEF DESCRIPTION OF THE DATA

1. MRID 49749002 "Standard Quantitative Disk Carrier Test Method, Test Organism: *Clostridium difficile* – spore form (ATCC 43598)" for CPPC Tsunami, FIS2014.0433, by Matthew Sathe. Study conducted at Accuratus Lab Services. Study completion date – September 17, 2015. Project Number A18664.

This study was conducted against *Clostridium difficile* – spore form (ATCC 43598). CPPC Tsunami, Batch No. 15SUK14, was tested using Accuratus Lab Services Protocol No. CX18052015.QDCT.2 (copy provided). The product was received as a pre-saturated towelette. The test substance liquid was extracted from the pre-saturated towelette by centrifuging in a conical centrifuge tube. The test substance was ready-to-

use after extraction from the towelette and was visually homogenous. Brushed stainless steel disk carriers (diameter = 1 cm, thickness = 0.7 mm) were used in the test. From a stock source, a stock plate of test organism was prepared. The plate was incubated for 44-52 hours at 35-37°C under anaerobic conditions. Following incubation, one 10 mL tube of Reinforced Clostridial Medium (RCM) was inoculated with test organism and incubated. Then, 30 CDC Anaerobic Blood Agar plates were inoculated with 100 µL of broth culture per plate. The inoculum was spread over the plates, inverted, and incubated 10 days at 35-37°C under anaerobic conditions.

Following 10 days of incubation, the growth was harvested from the plates by adding 5.0 mL of Phosphate Buffered Saline (PBS) with 0.1% Tween 80 to each plate and scraping each plate with a cell scraper. The liquid was removed from each plate and transferred to sterile 50 mL conical tubes. The suspension was centrifuge-concentrated at 3500 RPM for 38 minutes. Then the pellet was resuspended in 30.0 mL of PBS and 0.1% Tween 80. The suspension was centrifuge-concentrated two more times. The supernatant was removed and the pellet was resuspended in 4 mL of PBS and 0.1% Tween 80. The spore suspension was heated in a water bath for 9-11 minutes at 63-67°C. The spore suspension was evaluated for spore purity by microscopic analysis and demonstrated 98% purity. The spores were purified using HistoDenz and centrifugation. Following purification, the spore purity was 99% pure. Hydrochloric acid resistance was conducted and found acceptable. An organic soil load was added to give a final concentration of 0.25% Bovine Serum Albumin, 0.08% Bovine Mucin and 0.35% Yeast Extract.

Up to 20 sterile stainless steel disks were transferred to individual sterile Petri dishes matted with filter paper. Ten (10) µL of culture was placed in the center of each disk using a calibrated positive displacement pipettor and the inoculum was not spread. After all disks in the Petri dish were inoculated, the cover was replaced. The contaminated carriers were placed in a desiccator containing active desiccant. A vacuum was drawn and the carriers were dried for 2 hours under ambient conditions. At the end of the drying period, the carriers were examined to assure the inoculum had not run off the carrier. Any carriers showing signs of run-off were discarded. Each contaminated and dried carrier was placed into a separate sterile vial with the contaminated side facing up. Fifty (50) µL of the test substance was applied to the center of the disk using a positive displacement pipettor. Care was taken to ensure that the entire inoculated area on the disk was covered with test substance. The test substance was allowed to remain in contact with the disk for 2 minutes and 45 seconds at room temperature (21°C) and 48-51% relative humidity. Following the exposure time, 10 mL of neutralizer was added to the vial containing the carrier. The vial containing the carrier was vortex mixed for approximately 2-3 seconds. Once the entire set of carriers was neutralized, each was vortex mixed again for 30±5 seconds. For testing on 6/22/15, the test vial was filtered by transferring the liquid from each vial onto the surface of a 0.2 µm porosity filter membrane pre-wetted with approximately 10 mL of PBS and evacuating the contents. Approximately 20 mL of sterile PBS was added to the vial containing the carrier and the vial was vortex mixed. The rinse solution was filtered using the same filter membrane as the 10^0 dilution. This rinse step was repeated three times for a total of four rinses. The filter was rinsed with approximately 40 mL of sterile PBS. The contents were evacuated. Each filter membrane was removed aseptically from the filter unit and placed onto the surface of a BHIY-HT agar plate. For testing on 7/9/15, a ten-fold serial dilution (10^{-1}) of the neutralized test vials (10^0) was prepared by transferring 1.0 mL of the vial contents to 9 mL of PBS +0.1% Tween 80 prior to filtering the test vial. The entire serial dilution was filter plated. The remaining vial contents (10^0) were vortex mixed and filtered in its entirety in the same manner as the 6/22/15 testing. Subcultures were incubated anaerobically for 120±4 hours at 35-37°C in an inverted position. Following incubation, the number of survivors was determined. Study controls included Purity, Sterility, Neutralization Confirmation, Spore Titer, Carrier Population, and HCI Resistance.

Note: One protocol amendment was reviewed.

2. MRID 49749003 "Standard Quantitative Disk Carrier Test Method, Test Organism: *Clostridium difficile* – spore form (ATCC 43598)" for CPPC Tsunami, FIS2014.0433, by Matthew Sathe. Study conducted at Accuratus Lab Services. Study completion date – September 17, 2015. Project Number A18669.

This study was conducted against *Clostridium difficile* – spore form (ATCC 43598). CPPC Tsunami, Batch No. 15SUK15, was tested using Accuratus Lab Services Protocol No. CX18061715.QDCT.1 (copy provided). The product was received as a pre-saturated towelette. The test substance liquid was extracted from the pre-saturated towelette by centrifuging in a conical centrifuge tube. The test substance was ready-to-use after extraction from the towelette and was visually homogenous. Brushed stainless steel disk carriers (diameter = 1 cm, thickness = 0.7 mm) were used in the test. From a stock source, a stock plate of test organism was prepared. The plate was incubated for 44-52 hours at 35-37°C under anaerobic conditions. Following incubation, one 10 mL tube of Reinforced Clostridial Medium (RCM) was inoculated with test organism and incubated. Then, 30 CDC Anaerobic Blood Agar plates were inoculated with 100 µL of broth culture per plate. The inoculum was spread over the plates, inverted, and incubated 10 days at 35-37°C under anaerobic conditions. Following 10 days of incubation, the growth was harvested from the plates by adding 5.0 mL of Phosphate Buffered Saline (PBS) with 0.1% Tween 80 to each plate and scraping each plate with a cell scraper. The liquid was removed from each plate and transferred to sterile 50 mL conical tubes. The suspension was centrifuge-concentrated at 3500 RPM for 38 minutes. Then the pellet was resuspended in 30.0 mL of PBS and 0.1% Tween 80. The suspension was centrifuge-concentrated two more times. The supernatant was removed and the pellet was resuspended in 12 mL of PBS and 0.1% Tween 80. The spore suspension was heated in a water bath for 9-11 minutes at 63-67°C. The spore suspension was evaluated for spore purity by microscopic analysis and demonstrated 98% purity. The spores were purified using HistoDenz and centrifugation. Following purification, the spore purity was 99% pure. Hydrochloric acid resistance was conducted and found acceptable. An organic soil load was added to give a final concentration of 0.25% Bovine Serum Albumin, 0.08% Bovine Mucin and 0.35% Yeast Extract.

Up to 20 sterile stainless steel disks were transferred to individual sterile Petri dishes matted with filter paper. Ten (10) µL of culture was placed in the center of each disk using a calibrated positive displacement pipettor and the inoculum was not spread. After all disks in the Petri dish were inoculated, the cover was replaced. The contaminated carriers were placed in a desiccator containing active desiccant. A vacuum was drawn and the carriers were dried for 2 hours under ambient conditions. At the end of the drying period, the carriers were examined to assure the inoculum had not run off the carrier. Any carriers showing signs of run-off were discarded. Each contaminated and dried carrier was placed into a separate sterile vial with the contaminated side facing up. Fifty (50) µL of the test substance was applied to the center of the disk using a positive displacement pipettor. Care was taken to ensure that the entire inoculated area on the disk was covered with test substance. The test substance was allowed to remain in contact with the disk for 2 minutes and 45 seconds at room temperature (21°C) and 47% relative humidity. Following the exposure time, 10 mL of neutralizer was added to the vial containing the carrier. The vial containing the carrier was vortex mixed for approximately 2-3 seconds. Once the entire set of carriers was neutralized, each was vortex mixed again for 30±5 seconds. The test vial was filtered by transferring the liquid from each vial onto the surface of a 0.2 µm porosity filter membrane pre-wetted with approximately 10 mL of PBS and evacuating the contents. Approximately 20 mL of sterile PBS was added to the vial containing the carrier and the vial was vortex mixed. The rinse solution was filtered using the same filter membrane as the 10^0 dilution. This rinse step was repeated three times for a total of four rinses. The filter was rinsed with approximately 40 mL of sterile PBS. The contents were evacuated. Each filter membrane was removed aseptically from the filter unit and placed onto the surface of a BHIY-HT agar plate. Subcultures were incubated anaerobically for 120±4 hours at 35-37°C in an inverted position. Following incubation, the number of survivors was determined. Study controls included Purity, Sterility, Neutralization Confirmation, Spore Titer, Carrier Population, and HCl Resistance.

3. MRID 49749004 "Standard Quantitative Disk Carrier Test Method, Test Organism: *Clostridium difficile* – spore form (ATCC 43598)" for CPPC Tsunami, FIS2014.0433, by Matthew Sathe. Study conducted at Accuratus Lab Services. Study completion date – September 17, 2015. Project Number A18670.

This study was conducted against *Clostridium difficile* – spore form (ATCC 43598). CPPC Tsunami, Batch No. 15SUK16, was tested using Accuratus Lab Services Protocol No. CX18061715.QDCT.2 (copy provided). The product was received as a pre-saturated towelette. The test substance liquid was extracted from the pre-saturated towelette by centrifuging in a conical centrifuge tube. The test substance was ready-to-use after extraction from the towelette and was visually homogenous. Brushed stainless steel disk carriers (diameter = 1 cm, thickness = 0.7 mm) were used in the test. From a stock source, a stock plate of test organism was prepared. The plate was incubated for 44-52 hours at 35-37°C under anaerobic conditions. Following incubation, one 10 mL tube of Reinforced Clostridial Medium (RCM) was inoculated with test organism and incubated. Then, 30 CDC Anaerobic Blood Agar plates were inoculated with 100 µL of broth culture per plate. The inoculum was spread over the plates, inverted, and incubated 10 days at 35-37°C under anaerobic conditions.

Following 10 days of incubation, the growth was harvested from the plates by adding 5.0 mL of Phosphate Buffered Saline (PBS) with 0.1% Tween 80 to each plate and scraping each plate with a cell scraper. The liquid was removed from each plate and transferred to sterile 50 mL conical tubes. The suspension was centrifuge-concentrated at 3500 RPM for 38 minutes. Then the pellet was resuspended in 30.0 mL of PBS and 0.1% Tween 80. The suspension was centrifuge-concentrated two more times. The supernatant was removed and the pellet was resuspended in 12 mL of PBS and 0.1% Tween 80. The spore suspension was heated in a water bath for 9-11 minutes at 63-67°C. The spore suspension was evaluated for spore purity by microscopic analysis and demonstrated 98% purity. The spores were purified using HistoDenz and centrifugation. Following purification, the spore purity was 99% pure. Hydrochloric acid resistance was conducted and found acceptable. An organic soil load was added to give a final concentration of 0.25% Bovine Serum Albumin, 0.08% Bovine Mucin and 0.35% Yeast Extract.

Up to 20 sterile stainless steel disks were transferred to individual sterile Petri dishes matted with filter paper. Ten (10) µL of culture was placed in the center of each disk using a calibrated positive displacement pipettor and the inoculum was not spread. After all disks in the Petri dish were inoculated, the cover was replaced. The contaminated carriers were placed in a desiccator containing active desiccant. A vacuum was drawn and the carriers were dried for 2 hours under ambient conditions. At the end of the drying period, the carriers were examined to assure the inoculum had not run off the carrier. Any carriers showing signs of run-off were discarded. Each contaminated and dried carrier was placed into a separate sterile vial with the contaminated side facing up. Fifty (50) µL of the test substance was applied to the center of the disk using a positive displacement pipettor. Care was taken to ensure that the entire inoculated area on the disk was covered with test substance. The test substance was allowed to remain in contact with the disk for 2 minutes and 45 seconds at room temperature (21°C) and 46% relative humidity. Following the exposure time, 10 mL of neutralizer was added to the vial containing the carrier. The vial containing the carrier was vortex mixed for approximately 2-3 seconds. Once the entire set of carriers was neutralized, each was vortex mixed again for 30±5 seconds. The test vial was filtered by transferring the liquid from each vial onto the surface of a 0.2 µm porosity filter membrane pre-wetted with approximately 10 mL of PBS and evacuating the contents. Approximately 20 mL of sterile PBS was added to the vial containing the carrier and the vial was vortex mixed. The rinse solution was filtered using the same filter membrane as the 10^0 dilution. This rinse step was repeated three times for a total of four rinses. The filter was rinsed with approximately 40 mL of sterile PBS. The contents were evacuated. Each filter membrane was removed aseptically from the filter unit and placed onto the surface of a BHIY-HT agar plate. Subcultures were incubated anaerobically for 120±4 hours at 35-37°C in an inverted position. Following incubation, the number of survivors was determined. Study controls included Purity, Sterility, Neutralization Confirmation, Spore Titer, Carrier Population, and HCl Resistance.

4. MRID 49749005 "Wetness Determination for Towelette Products" for CPPC Tsunami, FIS2014.0433, by William Sanow. Study conducted at Accuratus Lab Services. Study completion date – September 16, 2015. Project Number A18900.

Three lots (15SUK14, 15SUK15, and 15SUK16) of the test substance, CPPC Tsunami, were examined

using the provided Accuratus Labs Protocol No. CX18071615.WET (copy provided). The product was received as a ready to use, pre-saturated towelette.
One towelette was used to wipe a glass (12 inch X 12 inch) carrier per lot of test substance. The procedure was recorded from the start to finish (copy of video provided). Prior to treatment, the carrier was weighed. The towelette was folded in half twice, once along the length and once along the width. The towelette was placed on the top left corner of the test carrier and wiped in an up and down motion, each stroke slightly overlapping the last, until the entire test carrier was completely covered for approximately 7 total strokes. A calibrated timer was initiated after the entire test surface was treated. The carrier was placed on the scale, the initial wet weight of carrier was taken, the carrier was allowed to be undisturbed for the exposure period of 3 minutes, and upon completion of the exposure period the final wet weight was taken. The test surface was wiped across a single sheet of unfolded cigarette paper immediately following final weighing to assist in visualization of wetness. Visual wetness of the cigarette paper was used to determine the presence or absence of carrier wetness.
For the gravimetric wetness test, one towelette was used to wipe 10 glass slide carriers for each lot under ambient conditions. Each carrier in its empty aluminum weigh boat was weighed. Each carrier was wiped and weighed again. The exposure period of 3 minutes began once the carrier was wiped. Each carrier was weighed once more after the exposure period. The carriers were then dried for 30 minutes at approximately 100-105°C and cooled at room temperature (21.5°C) for at least one hour prior to being weighed for the final time. The acceptance criterion for this procedure is that the weight following the exposure time is greater than the dried weight for all carriers tested.

Note: For the Gravimetric Wetness Confirmation calculation of the percentage of moisture loss, the following calculation was applied:
Percent (%) Moisture Loss = $[1 - (W_f - W_d) / (W_w - W_d)] \times 100$ Where:
W_d = Dried weight of treated slide
W_w = Weight of slide immediately following wiping W_f = Final weight of slide following exposure time

5. MRID 49749006 "Fungicidal Pre-Saturated Towelettes for Hard Surface Disinfection, Test Organism: *Candida glabrata* – (ATCC 32312)" for CPPC Tsunami, F2010.0203, by Becky Lien. Study conducted at Accuratus Lab Services. Study completion date – May 15, 2015. Project Number A17665.

CPPC Tsunami, Batch Nos. 14SUK23 and 14SUK24, were tested against *Candida glabrata* (ATCC 32312) using Accuratus Lab Services Protocol No. CX18120514.FTOW (copy provided). The product was received as a ready to use, pre-saturated towelette. A loopful of stock slant culture was transferred to an initial 10 mL of growth medium and incubated for 48-54 hours at 25-30°C. The test culture was vortex mixed and allowed to stand for at least 10 minutes prior to use. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass slide carriers per product lot were inoculated with 10 µL of 3 day old test organism culture. The carriers were dried for 30 minutes at 27.5-27.7°C at 67% relative humidity. Each inoculated carrier was treated with two passes, where one pass equals a back and forth motion for a total of 4 passes. One towelette was used to treat 10 carriers. A different section of towelette was used to wipe each carrier. The carriers were allowed to remain wet for 3 minutes at room temperature (23.67°C) and 10.88% relative humidity. Following exposure, individual carriers were transferred to 20 mL of Sabouraud Dextrose Broth containing 0.07% Lecithin, and 0.5% Tween 80 to neutralize. Within 25-60 minutes of the initial transfer, carriers were transferred to secondary neutralizing subcultures containing 20 mL of Sabouraud Dextrose Broth containing 0.07% Lecithin, and 0.5% Tween 80. All subcultures were incubated for 2 days at 25-30°C, and then examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population.

Note: Protocol amendment reported in the study was reviewed.

6. MRID 49749007 "Pre-Saturated Towelettes for Hard Surface Disinfection, Test Organism: *Enterococcus hirae* (ATCC 10541)" for CPPC Tsunami, F2010.0203, by Becky Lien. Study conducted at Accuratus Lab Services. Study completion date – May 15, 2015. Project Number A17674.

Two batches (Batch Nos. 14SUK23 and 14SUK24) of the product, CPPC Tsunami, were tested against *Enterococcus hirae* (ATCC 10541) using Accuratus Lab Services Protocol No. CX18120514.TOW.2 (copy provided). The product was received as a ready-to-use, pre-saturated towelette. A loopful of stock slant culture was transferred to an initial 10 mL of growth medium, mixed, and incubated for 24+/-2 hours at 35-37°C. A 10 µL aliquot was transferred to 10 mL of culture medium. The final test culture was incubated for 48-54 hours at 35-37°C. The test culture was vortex mixed and allowed to stand for at least 10 minutes prior to use. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass slide carriers per product lot were inoculated with 10.0 µL of test organism suspension. The carriers were dried for 30 minutes at 27°C at 65% relative humidity. Each carrier was treated with two passes where one pass equals a back and forth motion for a total of 4 passes. One towelette was used to treat 10 carriers. A different section of towelette was used to wipe each carrier. The carriers were allowed to remain wet for 30 seconds at 21°C and 15% relative humidity. Following exposure, individual carriers were transferred to 20 mL of Letheen Broth and 0.1% Sodium Thiosulfate. All subcultures were incubated for 48+/-2 hours at 35-37°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population.

7. MRID 49749008 "Pre-Saturated Towelettes for Hard Surface Disinfection, Test Organism: *Staphylococcus epidermidis* (coagulase-negative staphylococci) (ATCC 12228)" for CPPC Tsunami, F2010.0203, by Becky Lien. Study conducted at Accuratus Lab Services. Study completion date – May 15, 2015. Project Number A17666.

Two batches (Batch Nos. 14SUK23 and 14SUK24) of the product, CPPC Tsunami, were tested against *Staphylococcus epidermidis* (coagulase-negative staphylococci) (ATCC 12228) using Accuratus Lab Services Protocol No. CX18120514.TOW.1 (copy provided). The product was received as a ready-to-use, pre-saturated towelette. A loopful of stock slant culture was transferred to an initial 10 mL of growth medium, mixed, and incubated for 24+/-2 hours at 35-37°C. A 10 µL aliquot was transferred to 10 mL of culture medium. The final test culture was incubated for 48-54 hours at 35-37°C. The test culture was vortex mixed and allowed to stand for at least 10 minutes prior to use. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass slide carriers per product lot were inoculated with 10 µL of 48-54 hour old test organism suspension. The carriers were dried 30 minutes at 36.1- 36.2°C at 53.2-55.5% relative humidity. Each carrier was treated with two passes where one pass equals a back and forth motion for a total of 4 passes. One towelette was used to treat 10 carriers. A different section of towelette was used to wipe each carrier. The carriers were allowed to remain wet for 30 seconds at 21°C and 19% relative humidity. Following exposure, individual carriers were transferred to 20 mL of Letheen Broth containing 0.1% sodium thiosulfate to neutralize. All subcultures were incubated for 48+/-2 hours at 35-37°C, and then examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population.

8. MRID 49749009 "Virucidal Hard-Surface Efficacy Test for Pre-Saturated or Impregnated Towelettes – Middle East Respiratory Syndrome Coronavirus (MERS-CoV)" for CPPC Tsunami, FIS2014.0433, by Salimatu Lukula. Study conducted at MircoBioTest. Study completion date – September 28, 2015. Project Number 320-597.

Two batches (Batch Nos. 15SUK14 and 15SUK15) of the product, CPPC Tsunami, were tested against Middle East Respiratory Syndrome Coronavirus (MERS-CoV) using MicroBioTest Protocol No.

320.1.07.31.15 (copy provided). The product was received as a ready-to-use, pre-saturated towelette.
Vero E6 cells (ATCC CRL-1586) were used as host cells. Stock virus was thawed on the day of the test. The stock virus contained 5% organic soil load. Films of virus were prepared by spreading 1.0 mL of virus inoculum over a 10-square inch area of one glass carrier per lot. The virus films were dried at 20.0°C in a relative humidity of 50.6-51.7% for 30 minutes. Each carrier was treated with two passes where one pass equals a back and forth motion for a total of 4 passes. A different towelette was used to wipe each carrier. The carriers were allowed to remain wet for 1 minute at 20°C and 51.7-53.4% relative humidity. Following the exposure time, the virus and test substance mixture were neutralized with 1.0 mL of 1x Minimum Essential Medium (MEM) with 10% Fetal Bovine Serum (FBS), 4% HEPES, 0.01 N HCI, and 0.5% $Na_2S_2O_3$. The mixture was scraped to obtain a post-neutralized sample, which was serially diluted with 1x MEM and 2% FBS. Controls included plate recovery, neutralizer effectiveness/viral interference, cytotoxicity, viability, virus stock titer.

9. MRID 49749010 "Virucidal Hard-Surface Efficacy Test of Pre-Saturated or Impregnated Towelettes – SARS-Associated Coronavirus, ZeptoMetrix/CDC (CDC# 200300592)" for CPPC Tsunami, FIS2014.0433, by Salimatu Lukula. Study conducted at MircoBioTest. Study completion date – September 28, 2015. Project Number 320-598.

Two batches (Batch Nos. 15SUK14 and 15SUK15) of the product, CPPC Tsunami, were tested against SARS-Associated Coronavirus, ZeptoMetrix/CDC (CDC# 200300592) using MicroBioTest Protocol No. 320.2.07.31.15 (copy provided). The product was received as a ready-to-use, pre-saturated towelette. Vero E6 cells (ATCC CRL-1586) were used as host cells. Stock virus was thawed on the day of the test. The stock virus contained 5% organic soil load. Films of virus were prepared by spreading 1.0 mL of virus inoculum over a 10-square inch area of one glass carrier per lot. The virus films were dried at 21°C in a relative humidity of 41.0-41.8% for 30 minutes. Each carrier was treated with two passes where one pass equals a back and forth motion for a total of 4 passes. A different towelette was used to wipe each carrier. The carriers were allowed to remain wet for 1 minute at 21°C and 41.6-41.8% relative humidity. Following the exposure time, the virus and test substance mixture were neutralized with 1.0 mL of 1x Minimum Essential Medium (MEM) with 10% Fetal Bovine Serum (FBS), 4% HEPES, 0.01N HCI, and 0.5% $Na_2S_2O_3$. The mixture was scraped to obtain a post-neutralized sample, then serially diluted with 1x MEM and 2% FBS. Controls included plate recovery, neutralizer effectiveness/viral interference, cytotoxicity, viability, and virus stock titer.

10. MRID 49749011 "Virucidal Efficacy of Pre-Saturated Towelettes for Hard Surface Disinfection Virus: Enterovirus type D68" for CPPC Tsunami, FIS2014.0433, by Mary J. Miller. Study conducted at Accuratus Lab Services. Study completion date – September 23, 2015. Project Number A19018.

This study was conducted against Enterovirus type D68 using RD cells (ATCC CCL-136) as the host system. Two batches (15SUK14 and 15SUK15) of the product, CPPC Tsunami, were tested according to ATS Labs Protocol No. CX18073115.ENTV (copy provided). The product was received ready-to-use as pre-saturated towelette. Stock virus was prepared by collecting supernatant from infected culture cells. The cells were disrupted and centrifuged at 2000 RPM to remove debris. Supernatant was removed, aliquoted, and stored until use in the assay. The stock virus culture was adjusted to contain 5% fetal bovine serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were dried for 20 minutes at 15.5°C at 50% relative humidity. One replicate per product lot was tested. For each lot of product, separate dried virus films were wiped with a saturated towelette from each batch of test substance. Each carrier was divided into two sections for wiping. Each section was wiped using two passes, where one pass equals a back and forth motion, for a total of 4 passes. A new unused area of the folded towelette was exposed for each section. The sections were treated in such a way that overlapping was minimal. The treated dish was held covered for 1 minute at 20.0°C. Following exposure, a 2.00 mL aliquot of test medium was added and the plates were scraped with a cell scraper to re- suspend the contents. The virus-disinfectant mixtures then were passed

through individual Sephadex columns, and diluted serially in MEM supplemented with 2 % (v/v) heat inactivated FBS, 10 µg/mL gentamicin, 100 units/mL penicillin, 2.5 µg/mL amphotericin B, 2.0mM L-glutamine, 1 mM NEAA, and 1mM sodium pyruvate. RD cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 mL of each dilution. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2. The cultures were scored periodically for 7 days for the presence or absence of cytopathic effects, cytotoxicity, and viability. Controls included those for input virus, dried virus, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated with the Spearman Karber method.

11. MRID 49749012 "Virucidal Efficacy of Pre-Saturated Towelettes for Hard Surface Disinfection Virus: Influenza B virus" for CPPC Tsunami, FIS2014.0433, by Mary J. Miller. Study conducted at Accuratus Lab Services. Study completion date – September 23, 2015. Project Number A19019.

This study was conducted against Influenza B virus using MDCK (canine kidney) cells (ATCC CCL-34) as the host system. Two batches (15SUK14 and 15SUK15) of the product, CPPC Tsunami, were tested according to ATS Labs Protocol No. CX18073115.FLUB (copy provided). The product was received ready- to-use as pre-saturated towelette. Stock virus was prepared by collecting supernatant from infected culture cells. The cells were disrupted and centrifuged at 2000 RPM to remove debris. Supernatant was removed, aliquoted, and frozen. On the day of the assay, the stock virus was thawed and refrigerated until use. The stock virus culture was adjusted to contain 5% fetal bovine serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were dried for 20 minutes at 20.0°C at 50% relative humidity. One replicate per product lot was tested. For each lot of product, separate dried virus films were wiped with a saturated towelette from each batch of test substance. Each carrier was divided into two sections for wiping. Each section was wiped using two passes, where one pass equals a back and forth motion, for a total of 4 passes. A new unused area of the folded towelette was exposed for each section. The sections were treated in such a way that overlapping was minimal. The treated dish was held covered for 1 minute at 20.0°C. Following exposure, a 2.00 mL aliquot of test medium was added and the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures then were passed through individual Sephadex columns, and diluted serially in MEM supplemented with 2 µg/mL TPCK-trypsin, 25mM HEPES, 0.2 % bovine serum albumin (BSA) fraction V, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. RD cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 mL of each dilution. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2. The cultures were scored periodically for 7 days for the presence or absence of cytopathic effects, cytotoxicity, and viability. Controls included those for input virus, dried virus, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated with the Spearman Karber method.

12. MRID 49749013 "Virucidal Hard-Surface Efficacy Test of Pre-Saturated or Impregnated Towelettes – Measles Virus (ATCC VR-24)" for CPPC Tsunami, FIS2014.0433, by Salimatu Lukula. Study conducted at MircoBioTest. Study completion date – September 28, 2015. Project Number 320-599.

Two batches (Batch Nos. 15SUK14 and 15SUK15) of the product, CPPC Tsunami, were tested against Measles Virus (ATCC VR-24) using MicroBioTest Protocol No. 320.3.07.31.15 (copy provided). The product was received as a ready-to-use, pre-saturated towelette. Vero cells (ATCC CCL-81) were used as host cells. Stock virus was thawed on the day of the test. The stock virus contained 5% organic soil load. Films of virus were prepared by spreading 1.0 mL of virus inoculum over a 10-square inch area of one glass carrier per lot. The virus films were dried at 21°C in a relative humidity of 47.1-48.9% for 30 minutes. Each carrier was treated with two passes where one pass equals a back and forth motion for a total of 4 passes. A different towelette was used to wipe each carrier. The carriers were allowed to remain wet for 1 minute at 21°C and 47.1% relative humidity. Following the exposure time, the virus and test substance mixture were neutralized with 1.0 mL of RPMI with 1% Newborn Calf Serum (NCS), 4% HEPES, 0.025N HCI, and 0.5% $Na_2S_2O_3$. The mixture

was scraped to obtain a post-neutralized sample, and then serially diluted with 1x MEM and 1.0 µg/mL Trypsin. Controls included plate recovery, neutralizer effectiveness/viral interference, cytotoxicity, viability, and virus stock titer.

V. RESULTS

Hard Surface Sporicidal Disinfection Results:

MRID	Organism	Batch No. (Test Date)	Avg. Survivors/Test Carrier (Avg. Log_{10} Test Carriers)	Average Log10 Control Carriers	Percent Reduction (Log_{10})
49749002	*Clostridium difficile* (ATCC 43598)	15SUK14 (6/22/2015)	(>0.23)	6.32	<99.9999 (<6.09*)
		15SUK14 (7/9/2015)	(<0.27)	6.52	>99.9999 (>6.25)
49749003		15SUK15	<0.20	6.21	>99.9999 (>6.01)
49749004		15SUK16	<0.00	6.10	>99.9999 (6.10)

*Due to inconclusive results, testing was repeated with a modified filtration method to increase sensitivity.

Hard Surface Bactericidal and Fungicidal Disinfection Results:

MRID Number	Organism	No. Carriers Exhibiting Growth/Total Carriers		Carrier Population (Average Log10CFU/Carrier)
		Batch 14SUK23	Batch 14SUK24	
49749006	*Candida glabrata (ATCC 32312)*	1° = 0/10 2° = 0/10	1° = 0/10 2° = 0/10	4.64
49749007	*Enterococcus hirae (ATCC 10541)*	0/10	0/10	4.35
49749008	*Staphylococcus epidermidis* (coagulase-negative staphylococci) (ATCC 12228)	0/10	0/10	4.35

Wetness Results:

MRID 49749005	**Gravimetric Wetness** (Avg. % Moisture Loss) (Pass/Fail) 3 minute exposure	**Visual Wetness** (Pass/Fail) 3 minute exposure
15SUK14	5.3 (Pass)	Pass
15SUK15	3.9 (Pass)	Pass
15SUK16	4.3 (Pass)	Pass

Hard Surface Virucidal Disinfection Results:

MRID Number	Organism	Description	Batch 15SUK14	Batch 15SUK15	Dried Virus Control
49749009	MERS-Coronavirus (MERS-CoV)	10^{-2} to 10^{-6} dilutions	Complete Inactivation	Complete Inactivation	$10^{6.75}$
		TCID50/mL	$\leq$1.50	$\leq$1.50	
		Log_{10} Reduction	$\geq$5.25	$\geq$5.25	

49749010	SARS-Associated Coronavirus, ZeptoMetrix/CDC (CDC #200300592)	10^{-2} to 10^{-6} dilutions	Complete Inactivation	Complete Inactivation	$10^{6.75}$
		Log_{10} TCID50/mL	$\leq$1.5	$\leq$1.5	
		Log_{10} Reduction	$\geq$5.25	$\geq$5.25	
49749011	Enterovirus type D8	10^{-2} to 10^{-6} dilutions	Complete Inactivation	-	$10^{5.50}$
		10^{-1} to 10^{-6} dilutions	-	Complete Inactivation	
		TCID50/0.1mL	$\leq 10^{1.5}$	$\leq 10^{0.5}$	
		Log Reduction	$\geq$4.00	$\geq$5.00	
49749012	Influenza B Virus	10^{-1} to 10^{-6} dilutions	Complete Inactivation	Complete Inactivation	$10^{5.25}$
		TCID50/0.1mL	$\leq 10^{0.5}$	$\leq 10^{0.5}$	
		Log Reduction	$\geq$4.75	$\geq$4.75	
49749013	Measles Virus	10^{-2} to 10^{-6} dilutions	Complete Inactivation	Complete Inactivation	$10^{5.75}$
		Log_{10} TCID50/mL	$\leq$1.5	$\leq$1.5	
		Log_{10} Reduction	>4.25	>4.25	

VI. CONCLUSIONS

1. The submitted efficacy data support use of the product, CPPC Tsunami, FIS2014.0433, as a disinfectant with sporicidal activity against the following microorganism on hard, nonporous surfaces for a 2 minutes and 45 second contact time in the presence of soil:

MRID 49749002 *Clostridium difficile* (ATCC 43598)
MRID 49749003 *Clostridium difficile* (ATCC 43598)
MRID 49749004 *Clostridium difficile* (ATCC 43598)

Killing was observed in the subcultures of the required number of carriers tested against the required number of product lots. Carrier counts met acceptance criteria of 10^6 spores/carrier. The lab report showed a greater than 6-log reduction in viable spores when tested. Neutralizer confirmation testing demonstrated the neutralizer was effective in neutralizing antimicrobial activity of the product. Purity controls were reported as pure. Sterility controls did not show growth. Test spores showed resistance to acid for 10 minutes.

2. The submitted efficacy data support use of the product, CPPC Tsunami, F2010.0203, as a disinfectant with bactericidal activity against the following microorganisms on hard, nonporous surfaces with a 30 second contact time in the presence of soil:

MRID 49749007 *Enterococcus hirae* (ATCC 10541)
MRID 49749008 *Staphylococcus epidermidis* (coagulase-negative staphylococci) (ATCC 12228)

Killing was observed in the subcultures of the required number of carriers tested against the required number of product lots. Neutralization confirmation testing showed positive growth of the microorganisms. Purity controls were reported as pure. Viability controls were positive for growth. Sterility controls did not show growth.

3. The submitted efficacy data support the use of the product, CPPC Tsunami, F2010.0203, as a disinfectant with fungicidal activity against the following microorganism on hard, nonporous surfaces for a 3

minute contact time in the presence of soil:

MRID 49749006 *Candida glabrata* (ATCC 32312)

Killing was observed in the subcultures of the required number of carriers tested against the required number of product lots. Neutralization confirmation testing showed positive growth of the microorganisms. Purity controls were reported as pure. Viability controls were positive for growth. Sterility controls did not show growth.

4. The submitted efficacy data support the use of the product, CPPC Tsunami, FIS2014.0433, as a disinfectant with virucidal activity against the following microorganisms on hard, nonporous surfaces for a 1 minute contact time in the presence of soil:

MRID 49749009	MERS-Coronavirus (MERS-CoV)
MRID 49749010	SARS-Associated Coronavirus, ZeptoMetrix/CDC (CDC #200300592)
MRID 49749011	Enterovirus type D8, Strain US/KY/14-18953 (BEI Resources NR-49132)
MRID 49749012	Influenza B Virus, Strain B/Hong Kong/5/72 (ATCC VR-823)
MRID 49749013	Measles Virus (ATCC VR-24)

Recoverable virus titers of at least 10^4 were achieved. Complete inactivation (no growth) was indicated in all dilutions tested. At least a 3-log reduction in titer was demonstrated beyond the cytotoxic level.

VII. LABEL

1. The proposed label claims the product formulation, CPPC Tsunami, is a disinfectant with sporicidal activity against *Clostridium difficile* (ATCC 43598) spore on hard, nonporous surfaces with a 3 minute contact time: **These claims are acceptable as they are supported by the submitted data.**

2. The proposed label claims the product formulation, CPPC Tsunami, is a disinfectant against the following bacteria on hard, nonporous surfaces for a 30 second contact time in the presence of soil:

Enterococcus hirae (ATCC 10541)
Staphylococcus epidermidis (coagulase-negative staphylococci) (ATCC 12228)

These claims are acceptable as they are supported by the submitted data.

3. The proposed label claims the product formulation, CPPC Tsunami, is a disinfectant with fungicidal activity against *Candida glabrata* (ATCC 32312) on hard, nonporous surfaces for a 3 minute contact time in the presence of soil. **This claim is acceptable as it is supported by the submitted data.**

4. The proposed label claims the product formulation, CPPC Tsunami, is a disinfectant with virucidal activity against the following viruses on hard, nonporous surfaces for a 1 minute contact time in the presence of soil:

MERS-Coronavirus (MERS-CoV)
SARS-Associated Coronavirus, ZeptoMetrix/CDC (CDC #200300592)
Enterovirus type D8, Strain US/KY/14-18953 (BEI Resources NR-49132)
Influenza B Virus, Strain B/Hong Kong/5/72 (ATCC VR-823)
Measles Virus (ATCC VR-24)

These claims are acceptable as they are supported by the submitted data.

5. The applicant must make the following changes to the proposed (11/20/15) label:

- On page 7, delete this statement "**Daily use product with sporicidal efficacy**". It is a general sporicidal claims that can be use when tested against Agency recommended spores, *Bacillus subtilis* and *Clostridium sporogenes.*

- On pages 7 and 8, delete all instances of the terms "sporicide" and "sporicidal." The word "spores" may be used in association with *C. difficile* references.

- On page 8, delete "**in dirty conditions**" from this statement "Tested Clostridium difficile -or- C. diff -or- C. difficile spores in dirty conditions [with soil load]".Tested was conducted in the presence of 5% organic soil load considered visibly clean conditions.

- On page 8, delete references to UTIs or urinary tract infections, respiratory infections and qualify the terms "pseudomonocidal" and "staphylocidal" to the supporting tested organisms.

- On pages 8 and 9, delete exposure reduction claims, infection reduction claims and the term "outbreaks."

- On pages 8 and 9, revise all prevention of pathogen cross-contamination, transmission, or "spread" claims to specify "…on treated surfaces."